

D. REMARKS

Claims 1-3, 7, 8, 10, 11, 17, 19 and 21 have been amended to more particularly point out and distinctly claim the subject matter of the invention.

Claims 20 has been withdrawn without prejudice.

Claim 4 has been cancelled without prejudice.

The abstract has been amended to comply with MPEP 608.01(b).

Applicant believes that none of the amendments above add new matter to the specification.

PATENTABILITY ARGUMENTS

A. The 35 U.S.C. §112 Second Paragraph Rejections Should Be Withdrawn Because It Has Been Traversed.

The Examiner has rejected claims 1-13, 17, 19 and 21 under 35 U.S.C. §112 second paragraph because the Examiner feels that they fail to particularly point out and distinctly claim the subject matter which Applicant regards as his invention.

More particularly, the Examiner states that the term "insertable" in claim 1 is vague and indefinite. In addition, the Examiner states that it is unclear the relationship between the "lid" on line 3 with the "lid" on line 7 and its structural relationship to the other elements of the device. Applicant has amended claim 1 to replace the term "insertable" so that the claim now reads "said receptacle able to receive said matrix". In addition, Applicant has provided a structural relationship between the lid and the device by adding the phrase "affixed to said open end of said receptacle". In view of these amendments, Applicant respectfully requests that the Examiner remove this rejection.

The Examiner then rejects claims 2 and 3 for reciting "said radioactive waste" which is not considered an element of the device. In addition the Examiner states that it is unclear where in the specification the isotopes listed are disclosed. Applicant has amended claims 2 and 3 so that these claims now read in part "A device according to claim 1 further comprising radioactive waste wherein said radioactive waste comprises a radioactive isotope selected from the group consisting of...". In view of these amendments Applicant respectfully requests that the examiner remove this rejection.

The Examiner then asks the question as to where in the specification the isotopes ^{125}I , ^{131}I , ^{36}Cl , ^{33}P , ^{32}P , ^{35}S , ^{18}F , ^{15}O , ^{14}C , ^{13}N , ^{11}C , and ^3H are disclosed. Applicant reminds the

Examiner that the claims are an integral part of the specification (see 35 U.S.C. 112) and as such constitute a full and complete disclosure if one skilled in the art after reading the specification is able to make and use the invention. In this case, Applicant's invention is a device that reduces the volatility of radioactive waste consequently the volatility of a wide variety of radioactive compounds could be reduced by being deposited in Applicant's device. As such, those radioactive materials listed in claims 2 and 3 would be recognized by one skilled in the art as potential waste products from laboratory experiments that could be deposited in Applicant's invention to reduce their volatility. Consequently, the radioactive isotopes listed in claims 2 and 3 are disclosed in the specification in claims 2 and 3. No additional disclosure is necessary or required.

The Examiner further rejects claim 7 for reciting "said natural material" and claim 8 for reciting "said synthetic material" without proper antecedent basis. Applicant has amended these claims so that they now properly depend from claim 6. In view of these amendments, Applicant respectfully requests that the Examiner remove this rejection.

The Examiner then rejects claims 10, 11 and 19 because it is unclear whether Applicant is attempting to recite the term "phosphonate salts" or "phosphate salts". The Examiner further rejects claim 19 because it is unclear whether the term "parts" means parts by volume of parts by weight. Applicant has amended these claims replacing the term "phosphonate" with the term "phosphate". In addition, Applicant has amended claim 19 to include the phrase "by weight of" following the word "parts" at each place it occurs in the claim. In view of these amendments, Applicant respectfully requests that the Examiner remove this rejection.

Finally the Examiner rejects claim 21 because it is unclear as to the relationship of "a receptacle" to the "at least one receptacle", the use of the term "maybe" does not constitute a positive structural element and it is unclear as to the relationship between the "at least one lid" and the "a lid" as well as the structural relationship between the "at least one lid" to the other elements of the device. Applicant has amended claim 21 inserting the appropriate phrase "at least one" before the word "lid" in part a and before the word "receptacle" in both parts a and b. In addition, Applicant has replaced the phrase "that may be inserted into said receptacle" with the phrase "said receptacle able to receive said absorbent matrix". In view of these amendments, Applicant respectfully requests that the Examiner remove this rejection

B. The 35 U.S.C §102(b) Rejection Should
Be Withdrawn Because The Claimed Invention
Is Not Anticipated By The Cited Reference

The Examiner rejects claims 14 and 16-18 as being anticipated by Levy *et al.* patent no.: 4,081,402. Applicant respectfully disagrees. To maintain a rejection under 35 U.S.C. 102 (b) the reference must teach each and every aspect of the claimed invention. The Examiner states that Levy *et al.* teach an absorbent matrix comprising a humectant, a pH-stabilizing agent and an absorbent material. Applicant respectfully disagrees.

Applicant's invention comprises a composition to reduce the volatility of radioactive waste. This waste may come from a variety of sources and may comprise a radioactive material in a variety of solutions. Because of these various types solutions it "is extremely important to prevent the formation of radioactive gas that can occur under acidic conditions" (page 6 lines 26-27). Consequently, Applicant has provided a quantity of "about 1 to about 10 parts of a composition of disodium phosphate salts" (page 12 claim 19) integral to, and incorporated within, Applicant's composition. Absent the pH-stabilizing agent additional depositions within Applicant's device during normal and continued use within a laboratory could result in an adverse chemical reaction resulting in the release of radioactive gases.

Levy *et al.* teach the use of an absorbent matrix in which an absorbent material is dispersed in the absorbent matrix. More specifically, Levy *et al.* teach the use of this composition in immunoassays to preferentially absorb undesirable low molecular weight compounds from a biological sample so that the desirable high molecular weight compounds can be isolated and analyzed. The assay selected to demonstrate the invention of Levy *et al.* was a thyroxine radioimmunoassay, which uses radioactive iodine (^{125}I). However, the hydrophilic absorbents of Levy *et al.* could be used in a variety of assays having undesirable low molecular weight compounds, which are not radioactive. In fact, the hydrophilic absorbents of Levy *et al.* were not designed to reduce the volatility of radioactive waste, they are merely compositions for removal of undesirable low molecular weight compounds from a solution assay.

Levy *et al.* fails to teach the use of a pH-stabilizing agent in any of the compositions disclosed. The Examiner has noted that in the ^{125}I thyroxine radioimmunoassay protocol of Levy *et al.* (example 2) a phosphate buffer solution is added to the biological sample prior to the assay. However, this is not a teaching by Levy *et al.* of the need for a pH-stabilizing agent in their compositions to reduce the volatility of radioactive (^{125}I) waste product from the reaction. It is merely an artifact of the need to buffer the biological sample being tested to prevent undesirable reactions that could adversely effect the sample and the results of the assay.

Correspondingly, one skilled in the art could not use the Levy *et al.* compositions in a manner taught by Applicant for using Applicant's invention. Serious consequences and injury could result if waste materials were added which caused an adverse or violent reaction resulting in the emission of a radioactive gas because a pH-stabilizing agent was not provided integral to, and incorporated within, the Levy *et al.* compositions. No where in Levy *et al.* do they teach the purpose and need for a pH-stabilizing agent in their compositions, therefore the rejection based on 35 U.S.C. 102(b) cannot be maintained and Applicant respectfully requests that the Examiner removes this rejection.

C. The 35 U.S.C §103(a) Rejection Should Be
Withdrawn Because The Claimed Invention Is Not
Obvious In View Of The Cited Reference

In order to maintain a rejection under 35 U.S.C. 103(a) there must be some motivation to combine the teachings of the cited references, there must be a reasonable expectation of success when combining the teachings of the references and the references must teach or suggest all of the claim limitations.

The Examiner rejects claims 1-13 and 21 as being unpatentable over Levy *et al.* in view of Lennon *et al.* (U.S. 4,999,163). More specifically regarding claims 1 and 21, the Examiner states that Levy *et al.* disclose an absorbent matrix comprising a humectant, a pH-stabilizing agent and an absorbent material. In addition, the Examiner states that Levy *et al.* teaches that the absorbent matrix is insertable into at least one receptacle, however, Levy *et al.* fail to disclose a receptacle comprising a means for affixing a lid and a lid. The Examiner then provides Lennon *et al.* to demonstrate that one of ordinary skill in the art at the time of the invention could have provided a lid and means for affixing a lid to a receptacle. Applicant respectfully disagrees.

No where in Levy *et al.* do they teach the purpose and need for a pH-stabilizing agent provided integral to, and incorporated within, their compositions. Therefore, the cited references do not teach all of the claim limitations. Consequently, a rejection based on 35 U.S.C. 103(a) cannot properly be maintained and Applicant respectfully requests that the Examiner remove this rejection.

The Examiner then rejects claim 2 and 3 stating that no further structural limitations are recited and therefore the modified apparatus of Levy *et al.* meets the claim. Specifically Levy *et al.* disclose an apparatus that may be used for the radioimmunoassay of antigens with ¹²⁵I or ³H. As provided above Applicant has amended claims 2 and 3 to properly incorporate the additional structural limitations of a "radioactive waste". Consequently, a rejection based on 35 U.S.C. 103(a) cannot properly be maintained and Applicant respectfully requests that the Examiner remove this rejection.

The Examiner further rejects claims 4 and 5 stating that Levy *et al.* disclose that the absorbent matrix may be deposited within a cylinder or article constructed of glass or inert plastic. The Examiner further cites Lennon *et al.* to demonstrate that a glass and plastic receptacle are conventionally known in the art. Applicant respectfully disagrees.

Both claims 4 and 5 depend from claim 1, which provides that the absorbent matrix comprises a humectant, a pH-stabilizing agent, and an absorbent material. No where in Levy *et al.* do they teach the purpose and need for a pH-stabilizing agent provided integral to, and incorporated within, their compositions. Therefore, the cited references do not teach all of the claim limitations. Consequently, a rejection based on 35 U.S.C. 103(a) cannot properly be maintained and Applicant respectfully requests that the Examiner remove this rejection.

The Examiner further rejects claim 6 stating that Levy *et al.* further disclose that the absorbent matrix is constructed of one or more synthetic materials. Applicant respectfully disagrees.

Claim 6 depends from claim 1, which provides that the absorbent matrix comprises a humectant, a pH-stabilizing agent, and an absorbent material. No where in Levy *et al.* do they teach the purpose and need for a pH-stabilizing agent provided integral to, and incorporated within, their compositions. Therefore, the cited references do not teach all of the claim limitations. Consequently, a rejection based on 35 U.S.C. 103(a) cannot properly be maintained and Applicant respectfully requests that the Examiner remove this rejection.

The Examiner further rejects claim 7 stating that Levy *et al.* is silent as to whether the absorbent matrix may comprise a natural material, however, the Examiner states that it would have been obvious for one skilled in the art to use natural materials and cited Lennon *et al.* to demonstrate her point. Applicant respectfully disagrees.

Claim 7 depends from claim 6, which depends from claim 1 and provides that the absorbent matrix comprises a humectant, a pH-stabilizing agent, and an absorbent material. No where in Levy *et al.* do they teach the purpose and need for a pH-stabilizing agent provided integral to, and incorporated within, their compositions. Therefore, the cited references do not teach all of the claim limitations. Consequently, a rejection based on 35 U.S.C. 103(a) cannot properly be maintained and Applicant respectfully requests that the Examiner remove this rejection.

The Examiner further rejects claim 8 stating that Levy *et al.* further disclose that the synthetic material may comprise polyacrylamide and hydrophilic polymers. Applicant respectfully disagrees.

Claim 8 depends from claim 6, which depends from claim 1 and provides that the absorbent matrix comprises a humectant, a pH-stabilizing agent, and an absorbent material. No where in Levy *et al.* do they teach the purpose and need for a pH-stabilizing agent provided integral to, and incorporated within, their compositions. Therefore, the cited references do not teach all of the claim limitations. Consequently, a rejection based on 35 U.S.C. 103(a) cannot properly be maintained and Applicant respectfully requests that the Examiner remove this rejection.

The Examiner further rejects claim 9 stating that Levy *et al.* is silent as to whether the absorbent matrix may comprise unidirectional fibers, however, the Examiner cites Lennon *et al.* who teach an absorbent plug of conventionally known materials such as cotton fibers and having capillary passages extending therethrough which are both transverse to and generally parallel to the surfaces at the upper and lower ends of the plug. Applicant respectfully disagrees.

Claim 8 depends from claim 1, which provides that the absorbent matrix comprises a humectant, a pH-stabilizing agent, and an absorbent material. No where in Levy *et al.* do they teach the purpose and need for a pH-stabilizing agent provided integral to, and incorporated within, their compositions. Therefore, the cited references do not teach all of the claim limitations. Consequently, a rejection based on 35 U.S.C. 103(a) cannot properly be maintained and Applicant respectfully requests that the Examiner remove this rejection.

The Examiner further rejects claims 10 and 11 stating that Levy *et al.* further disclose that the pH-stabilizing reagent may comprise a dibasic phosphate salt. Applicant respectfully disagrees.

Both claims 10 and 11 depend from claim 1, which provides that the absorbent matrix comprises a humectant, a pH-stabilizing agent, and an absorbent material. As more fully stated above in Applicant's traversal of Examiner's 102(b) rejection, no where in Levy *et al.* do they teach the purpose and need for a pH-stabilizing agent provided integral to, and incorporated within, their compositions. Therefore, the cited references do not teach all of the claim limitations. Consequently, a rejection based on 35 U.S.C. 103(a) cannot properly be maintained and Applicant respectfully requests that the Examiner remove this rejection.

The Examiner further rejects claim 12 stating that Levy *et al.* further disclose that the absorbent material may comprise polymeric resins. Applicant respectfully disagrees.

Claim 12 depends from claim 1, which provides that the absorbent matrix comprises a humectant, a pH-stabilizing agent, and an absorbent material. No where in Levy *et al.* do they teach the purpose and need for a pH-stabilizing agent provided integral to, and incorporated within, their compositions. Therefore, the cited references do not teach all of the claim limitations. Consequently, a rejection based on 35 U.S.C. 103(a) cannot properly be maintained and Applicant respectfully requests that the Examiner remove this rejection.

The Examiner further rejects claim 13 stating that Levy *et al.* further disclose that the absorbent material may comprise activated charcoal. Applicant respectfully disagrees.

Claim 13 depends from claim 1 and provides that the absorbent matrix comprises a humectant, a pH-stabilizing agent, and an absorbent material. No where in Levy *et al.* do they teach the purpose and need for a pH-stabilizing agent provided integral to, and incorporated within, their compositions. Therefore, the cited references do not teach all of the claim limitations. Consequently, a rejection based on 35 U.S.C. 103(a) cannot properly be maintained and Applicant respectfully requests that the Examiner remove this rejection.

The Examiner further rejects claim 15 stating that Levy *et al.* is silent as to whether the absorbent matrix may comprise unidirectional fibers, however, the Examiner cites

Lennon *et al.* who teach an absorbent plug of conventionally known materials such as cotton fibers and having capillary passages extending therethrough which are both transverse to and generally parallel to the surfaces at the upper and lower ends of the plug. Applicant respectfully disagrees.

Claim 15 depends from claim 14, which provides that the absorbent matrix comprises a humectant, a pH-stabilizing agent, and an absorbent material. No where in Levy *et al.* do they teach the purpose and need for a pH-stabilizing agent provided integral to, and incorporated within, their compositions. Therefore, the cited references do not teach all of the claim limitations. Consequently, a rejection based on 35 U.S.C. 103(a) cannot properly be maintained and Applicant respectfully requests that the Examiner remove this rejection.

The Examiner further rejects claim 19 stating that Levy *et al.* disclose an absorbent matrix that comprises glycerol, dibasic potassium phosphate and activated carbon, however Levy *et al.* is silent as the specific disodium phosphate salts. The Examiner states that it would have been obvious for one skilled in the art at the time of the invention to substitute disodium phosphate salts for dibasic potassium salts and cites Dean *et al.* to support her contention. In addition Levy *et al.* is silent as to the specific composition by parts of the glycerol, dibasic potassium salt and activated charcoal. However, Levy *et al.* do provide that the amount of glycerol added will depend on the level of hydration desired, that the amount of pH-stabilizer would depend on the desired pH level and the amount of activated charcoal would depend on the dimensions of the charcoal matrix. Finally the Examiner states that Levy *et al.* disclose the use of 20 grams of activated charcoal for forming disks for later insertion into tubes. Consequently it would have been obvious for one skilled in the art to modify the parts of activated charcoal to be about 0.5 to 10 parts by simply modifying the dimensions of the disks, depending on the intended use. Applicant respectfully disagrees.

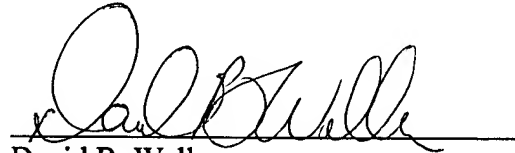
Claim 19 depends from claim 14, which provides that the absorbent matrix comprises a humectant, a pH-stabilizing agent, and an absorbent material. No where in Levy *et al.* do they teach the purpose and need for a pH-stabilizing agent provided integral to, and incorporated within, their compositions. Therefore, the cited references do not teach all of the claim limitations. Consequently, a rejection based on 35 U.S.C. §103(a) cannot properly be maintained and Applicant respectfully requests that the Examiner remove this rejection.

CONCLUSION

In view of the above arguments Applicant has amended the claims and demonstrated that the invention as claimed satisfies the statutory requirements for patentability. Applicant respectfully requests that the Examiner issue an allowance of the claims.

Respectfully submitted,

Date: 21 April 2003



David B. Waller

Registration No. 43,978

David B. Waller & Associates
5677 Oberlin Drive, Suite 214
San Diego, CA 92121

Telephone: (858) 457-2014
Facsimile: (858) 457-2308
E-mail: dwaller@cnmnetwork.com